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| APPLICATION NO.                        | FILING DATE     | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-----------------|----------------------|---------------------|------------------|
| 10/511,155                             | 10/14/2004      | Oliver Schadt        | MERCK-2932          | 9151             |
| 23599                                  | 7590 05/08/2006 |                      | EXAM                | IINER            |
| MILLEN, WHITE, ZELANO & BRANIGAN, P.C. |                 |                      | GRAZIER, NYEEMAH    |                  |
|  | NDON BLVD.      |                      | ART UNIT            | PAPER NUMBER     |
| SUITE 1400                             |                 | •                    | AKTONII             | TATER NOMBER     |
| ARLINGTON                              | N, VA 22201     |                      | 1626                |                  |

DATE MAILED: 05/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|   | Application No.   | Applicant(s)                     |  |  |  |
|---|---|----------------------------------|--|--|--|
|   | 10/511,155  | SCHADT ET AL.                    |  |  |  |
| Office Action Summary   | Examiner  | Art Unit                         |  |  |  |
|   | Nyeemah Grazier   | 1626                             |  |  |  |
| The MAILING DATE of this communication app  | ears on the cover sheet with the c                                  | orrespondence address            |  |  |  |
| Period for Reply  |   |                                  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |   |                                  |  |  |  |
| Status  |   |                                  |  |  |  |
| <ul> <li>1) ⊠ Responsive to communication(s) filed on 27 February 2006.</li> <li>2a) ☐ This action is FINAL. 2b) ⊠ This action is non-final.</li> <li>3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.</li> </ul>   |   |                                  |  |  |  |
| Disposition of Claims   |   |                                  |  |  |  |
| <ul> <li>4) ☐ Claim(s) 1-19 is/are pending in the application.</li> <li>4a) Of the above claim(s) 18 and 19 is/are withdrawn from consideration.</li> <li>5) ☐ Claim(s) is/are allowed.</li> <li>6) ☐ Claim(s) 1-4 and 12-16 is/are rejected.</li> <li>7) ☐ Claim(s) 2-17 is/are objected to.</li> <li>8) ☐ Claim(s) are subject to restriction and/or election requirement.</li> </ul>   |   |                                  |  |  |  |
| Application Papers  |   |                                  |  |  |  |
| 9) The specification is objected to by the Examiner.  |   |                                  |  |  |  |
| 10) The drawing(s) filed on is/are: a) acc  | epted or b) objected to by the                                      | e 37 CFR 1 85(a)                 |  |  |  |
| Applicant may not request that any objection to the   | tion is required if the drawing(s) is o                             | niected to. See 37 CFR 1.121(d). |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.  |   |                                  |  |  |  |
| Priority under 35 U.S.C. § 119  |   |                                  |  |  |  |
| <ul> <li>12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a)  All b)  Some * c) None of: <ol> <li>1.  Certified copies of the priority documents have been received.</li> <li>2.  Certified copies of the priority documents have been received in Application No</li> <li>3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> </ol> </li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>   |   |                                  |  |  |  |
| Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  Paper No(s)/Mail Date 10/14/04.  | 4) Interview Summa Paper No(s)/Mail 5) Notice of Informal 6) Other: |                                  |  |  |  |

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### DETAILED ACTION

FIRST ACTION ON THE MERITS

#### I. ACTION SUMMARY

Claims 1-17 (in part) are currently pending. Claims 18 and 19 are withdrawn from further consideration by the Examiner because Claims 18-19 are drawn to a non-elected invention. 37 C.F.R. § 1.142(b).

### II. PRIORITY

This application is a 371 of PCT/EP03/03806, filed April 11, 2003 which claims priority under 35 U.S.C. 119 (a-d) foreign application Germany 10217006.1 filed on April 16, 2002. However, an English translation of the foreign priority document should be submitted to the Office in the next reply.

## III. INFORMATION DISCLOSURE STATEMENT

The information disclosure statement (IDS) submitted on October 14, 2004 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

### IV. LACK OF UNITY IF INVENTION/ELECTION

# A. Election: Applicant's Response

Applicant's election of Group VIII, claims 1-17 in the response filed on February 27, 2006 is acknowledged. The applicant traverses on the grounds that the finding of lack of unity of invention in the Action dated January 25, 2006 was improper because the invention is drawn to an indole with a side chain, which is the "common structure". (See Remarks, p. 2, filed February 27, 2006).

The traversal is not persuasive because the core structure does not have contribution over the art and therefore is not a special technical feature. See Action, filed January 25, 2006 at page

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8. Thus, lack of unity of invention has been established. Additionally, because of the plethora of classes and subclasses in each of the Inventions, a serious burden is imposed on the examiner to perform a complete search of the defined areas. Lack of restriction would impose a serious burden on the Examiner. Thus, based on the abovementioned rationale, Lack of Unity of Inventions set forth in the instant application is proper.

The requirement is still deemed proper and is therefore made FINAL.

## B. Status of the Claims

# i. Scope of the Elected Subject Matter

Applicant has elected with traverse the following formula as a provisional specie election.

Thus, for search purposes the elected invention are the compounds of formula (I) wherein:

R<sup>1</sup>, A, D-E, Het, Ar, Hal, w, n, g and m are recited in claim 1;

X<sup>1</sup> is (CHR7)g;

E and G together form a saturated 1,4-diazine ring wherein the additional nitrogen is linked directly to variable Z;

X2 is a bond; and

Z is a benzofuranyl ring.

# ii. Extended Prior Art Search M.P.E.P. §803.02

If upon examination of the elected species, no prior art is found that would anticipate or render obvious the instant invention based on the elected species, the search of the Markush-type claim will be extended. See M.P.E.P. § 803.02 (2001). If prior art is then found that anticipates or renders obvious the non-elected species, the Markush-type claim will be rejected. It should be noted that

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the prior art search will not be extended unnecessarily to cover <u>all non-elected</u> species. Should Applicant overcome the rejection by amending the claim, the amended claim will be reexamined. <u>Id.</u> The prior art search will be extended to the extent necessary to determine patentability of the Markush-type claim. <u>Id.</u> In the event prior art is found during reexamination that renders obvious or anticipates the amended Markush-type claim, the claim will be rejected and the action made final. <u>Id.</u>

As indicated above, Examiner searched the compound based on the elected species, exemplified above, in response to the requirement to restrict the products of Formula (I). However, there was no prior art of record that anticipated or rendered obvious the elected species and therefore the scope of the subject matter was **extended or broaden** in pursuant to M.P.E.P. § 803.02.

The prior art search was extended to also include **Z** wherein **Z** is an aromatic heterocyclic polycyclic ring system having 4 to 9 carbons and whereby the aromatic heterocyclic contains from 1 to 4 heteroatoms selected, independently of one another, from N, O, and S.

# iii. Non-elected Subject Matter Withdrawn 37 C.F.R. §1.142(b)

The non-elected subject matter are the compounds of formula (I) wherein:

**D-E** is R2R3-C-CR4R5;

**X1** is (CHR7)h-Q-(CHR8)k;

E is H, A, (CH2)nHet, (CH2)nAr or cycloalkyl having 3 to 7 carbons;

G is an optionally substituted alkylene radical having 1 to 4 carbon atoms;

E and G together form a 5 or 7 membered ring having 1, 2, or 3 further heteroatoms selected from N, O and S.

X2 has the meanings indicated for X1;

Z is H or is a saturated mono- or polyethylenically unsaturated or aromatic carbocyclic radical having from 5 to 10 carbon atoms or a saturated, mono or polyethylenically unsaturated heterocyclic radical having 4 to 9 carbon atoms whereby the ring contains 1 to 4 heteroatoms selected from N, O and S.

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### V. REJECTION(S)

## Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 12-16 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility.

Claims 12-16 provides for the use of compounds of formula (I), but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 12-16 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd. App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

# Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12-16 also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well

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established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1-4 recite the limitation "derivatives." The specification does not have support for "derivatives." The specification does not define the term and does not teach what is meant by "derivatives" and therefore the claim is indefinite. The applicant is welcome to specifically point to the specification to show proof of support in the next reply. The examiner will consider the evidence, if provided. Otherwise, to obviate the rejection, the applicant should delete the term.

Claims 2 and 3 recite a range within a range. Namely, the rejected claims recites in various places phrases such as "and in particular" or "preferably." The rejected phrases refer to representatives of variables of formula (1) and the phrases are generally recited after the variables have been defined and seeks to further recite a "preferred" range of the said variable. Claims are indefinite where the claims refers to a range within a range. To obviate the rejection, the phrases should be deleted and if desired a claim may further depend from the claim to further define the particular variable.

# Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Peglion, et al., EP 1078928 A1 (US Equivalent = US 6,399,616 B1). Peglion et al. teaches pyridine compounds

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useful as treatments disorders related to the central serotonergic system. The instant invention is anticipated by example 10, which discloses the specie compound entitled 4-{4-[2-(1H-Indol-5-yl)ethyl]-1-piperazinyl}furo[3,2=c]pyridine. (See, col. 15, ll. 26-28). Thus, instant formula (I) wherein D-E is CH=CH, R1 is H, p is 0, X is (CH2)2, E and G together with the N form 1,4-diazine, X2 is a bond and Z is an "aromatic bicyclic heterocyclic radical having 7 carbon atoms and containing oxygen and nitrogen as hetero atoms.

### VI. OBJECTION(S)

Claims 1-4 are objected to as containing non-elected subject matter. To obviate this objection, the applicant should amend the claims by deleting the non-elected variables and or the non-elected subject matter defined for each variable in the next reply.

Claims 8-11 are objected to under 37 CFR 1.75 as being a substantial duplicate of claim 1 because claims 8-11 do not further limit the scope of te invention (e.g. composition of matter) as intended uses do <u>not</u> have patentable weight. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). To obviate the objection, the Applicant should cancel claims 8-11.

Claims 2-17 are objected to for being dependent upon a rejected claim.

### VII. CONCLUSION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nyeemah Grazier whose telephone number is (571) 272-8781. The examiner can normally be reached on Monday through Thursday and every other Friday from 8:30 a.m. - 6:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. M<sup>©</sup>Kane, can be reached on (571) 272 - 0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Very truly yours,

Nyeemah Grazier, Esq

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